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ABSTRACT

Diabetes mellitus is a condition that lends itself to the use of telemedicine and technology because its management relies heavily on the collection, sharing, and interpretation of blood glucose data by the patient and healthcare provider. We studied whether or not we could improve the blood sugars of poorly controlled diabetics ($A_1C > 8.0\%$) by giving them one of three technologies to communicate their blood sugar results from home to their provider. Poorly controlled type 1 and 2 diabetic patients were prospectively randomized to "routine care" (n=67) or "technology" (n=104). Patients in the latter group were further randomized to one of three technologies – modem (n=37), WebTV (n=22), internet accessible computer (n=45) - which connected their glucose meter to their provider via a secure password-protected website maintained by HealthSentry. Patients in the WebTV and computer groups could review their own data on the website, whereas those using the modem could not. "Routine care" patients were seen by their provider as needed but no less than every 3 months and treated according to clinical practice guidelines. The patients in the "technology" group were similarly seen but were also instructed to download their blood glucose values weekly by the assigned technology. The HealthSentry software accepts downloads from any brand of glucose meter which it then analyzes and displays in tabular and graphic formats. Treatment recommendations were then made based on the data. Data for the first 92 patients have been analyzed (45 "routine care" and 47 "technology"). Since there were no difference among the 3 "technology" groups, their results have been grouped together. Furthermore, patients were equally matched in each group with respect to demographics and pre-study glycemic control. Patients receiving "routine care" significantly improved their mean (+/- sem) A1c over 6 months (10.05 ±0.32 % to 8.32 +/- 0.30%; $p < 0.01$) as did those in the "technology" group (9.55 +/- 0.24% to 7.83 +/- 0.22%; $p < 0.01$). To date, the "technology" group did not significantly improve any more than those receiving "routine care," nor were there differences among the "technology" groups. However, the improvement in glycemic control was achieved without the weight gain or increases in triglyceride levels seen in the "routine care" group. The number of clinic visits in 6 months was slightly but not significantly fewer in the "technology" group (2.7+/-0.3) compared with "routine care" (3.2+/-0.3). The "technology" group had a higher number of telephone consultations (8.4+/-0.7 vs. 4.6+/-0.7 ; $p < 0.005$). There were no differences in hemoglobin, ALT, AST, or microalbumin/creatinine ratios after 6 months in any of the groups.

The data indicate that remote monitoring of patients' glycemic status is feasible using a web based platform. However, these telemedicine technologies did not improve glycemic control above that of "routine care" although appear to have done so without increases in weight or triglycerides. The ability to show any advantage of these technologies in glycemic control, per se, may have been limited by the fact that all patients were treated by endocrinologists and their subspecialty-trained nurse practitioners. These tools may be more effective in the hands of patients who are seen by providers, e.g. family practitioners, general internists, physicians assistants, and non-specialist nurse practitioners, whose time is more limited and management skills are not as advanced as those of specialists.

BODY

Diabetes mellitus (DM) which affects approximately 19 million people in the United States is associated with devastating complications in both personal and financial terms. Diabetes is the leading cause of blindness, non-traumatic amputations, and renal failure in adults and reduces life expectancy by 5-10 years. The direct and indirect costs of DM care were $98 billion in 1997 with the cost of medical care per capita approximately $10,000 per year compared with $2700 per year for those without DM. The vast majority of these costs are related to hospitalizations resulting from the chronic complications of DM, with only about 15% of the costs attributable to professional visits and pharmaceuticals. The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) conclusively proved that improved glycemic control was important in reducing complications. Together, these studies showed that for every 1% decrease in Hemoglobin A_{1c} (A_{1c}), there is a 25% decrease in microvascular complications. Based on these studies, the American Diabetes Association (ADA) recommends that the goal for A_{1c} should be below 7% (normal 4-6.1%), and the American Association of Clinical Endocrinologists recommends that it should be below 6.5% (corresponding to an average blood glucose of 150 and 135 mg/dL, respectively, [normal 70-126 mg/dl]). Home blood glucose monitoring (HBGM) has become one of the essential tools in achieving improved glycemic control. There is a direct, strongly positive relationship between the frequency of monitoring and glycemic control. Accordingly, the ADA recommends 3 or more measurements of blood glucose per day in patients with type 1 DM and that the frequency of HBGM should be "sufficient to facilitate reaching glucose goals" in patients with type 2 DM.

Despite increased accessibility, affordability, and accuracy of blood glucose meters, glycemic control remains sub-optimal in most patients. Of the more than 6000 active patients with DM in the Walter Reed Health Care System (WRHCS) -- where there is no cost to the patient for a meter and strips (or any other aspects of their health care) -- 47% have hemoglobin A_{1c} between 7% and 9.5%, and for 10% it is above 9.5%.

We hypothesized that more patients do not reach appropriate goals for glycemic control because the healthcare provider is unable to monitor and/or review the patient's glucose test results in a frequent, timely and efficient interactive manner. The patient usually brings his/her handwritten logbook and/or meter to the clinic where the data are reviewed manually. Occasionally the patient will bring a memory-equipped meter to the clinic, where it may be downloaded to the provider's computer and analyzed. However, this is time consuming and occurs only in a small minority of situations. Manual review of the records precludes any statistical and graphical analysis of the data and often limits the provider's ability to recognize patterns and trends in the glucose measurements. Moreover, this approach is a time-consuming and an inefficient use of both the provider's and patient's time. All the major glucose meters manufacturers provide software for data analysis (a few of which are web-based) but each has its own proprietary software for data analysis and its own unique connecting cables for downloading data, requiring a multiplicity of connecting cables for the provider's computer.

Although many studies have trumpeted the potential advantages of web-based management of DM, most have addressed using the web for patient education, performance monitoring, risk stratification, and case management by nurses. Others have been initiated or are in a pilot stage. Only a few studies have shown that using the web improves glycemic control or can replace a clinic visit. In one recent study, a web-based decision support system (DSS) improved compliance with generally recognized process measures of DM care (e.g. the number of A_{1c} and

LDL tests obtained) but did not improve the actual A_{1c} level. However, analysis of patients' home blood glucose data was not studied.

Summary of Research Plan

a. Subjects:

Adult non-pregnant patients with diabetes mellitus type 1 and 2 (ages 18 – 65 years) were invited to participate by the attending nurse practitioner, study coordinator, and/or principal investigator during a regular Diabetes Institute visit at one of the five clinics of the WRHCS. Only diabetic patients identified as 'poorly controlled' (e.g., hemoglobin $A_1C \geq 8\%$) were asked to volunteer. Informed consent was obtained after giving the patient sufficient time to consider his/her participation.

Inclusion and Exclusion Criteria:

Patient inclusion criteria are listed below. Participating patients:

- Had a diagnosis of diabetes mellitus for over three months
- Had a history of poor glycemic controls (hemoglobin $A_1C \geq 8\%$)
- Were over 18 years of age
- Were medically stable (e.g., no myocardial infarction, stroke, major surgery, no major psychiatric events (suicide events/attempts) within the previous 6 months.

Patient exclusion criteria are listed below. Participating patients must not have been:

- Unwilling/unable to receive training
- Unable to communicate in written and spoken English
- Pregnant
- An organ (kidney, pancreas, liver) transplant recipient
- Severely impaired in dexterity, visual acuity, or intellectual capacity
- An abuser of alcohol or of illegal substances within the past two years.

Patient discontinuation criteria are listed below. Participating patients were discontinued from the study if:

- Pregnancy occurred
- A protocol violation occurred
- They were lost to follow-up because of a move or transfer outside of the Washington, DC metropolitan area
- They withdrew their consent
- They died
- They developed a severe visual impairment

b. Study Design:

This study was a prospective randomized clinical trial of 6-month duration. The initial plan was for up to three hundred and twenty-four patients to be included. Approximately one hundred fifty of the study participants were to be randomized to Group 1 (the "routine care" group) to receive standard Diabetes Institute (DI) medical care. Group 1 included those that had been pre-randomized to this group because of lack of access to the Internet. Standard DI care is founded on a specialty practice guideline-based model using endocrine trained nurse

practitioners that co-manage the patients' diabetes problems with the primary care provider. Patients in this group received a level of care that is above that routinely provided by the WRAMC. The remaining approximately 150 patients were to be randomized using a random number generator to one of three technology groups: Group 2 (telephone and modem technology (50 patients)); Group 3 (internet technology – WebTV (50 patients)); Group 4 (internet technology – computer (50 patients)).

ROUTINE CARE: Group 1.
During the patient's initial visit, a comprehensive medical history was taken to confirm the diagnosis, review and reassess the previous treatment, evaluate past and present degrees of glycemic control, determine the presence or absence of chronic complications of diabetes, assist in formulating a management plan, and provide a basis for continuing care. A physical examination was performed during the initial evaluation. Each patient underwent any routine laboratory tests as deemed appropriate by the health care provider. A diabetes management plan was formulated as an individualized therapeutic alliance among the patient and family, the provider, and other members of the health care team skilled in diabetes management.

RESEARCH: Groups 2, 3 and 4.
Patients assigned to Group 2 transmitted their glucose measurements through a modem compatible to their glucometer to a specially designed secure website. Group 3 transmitted their glucose measures via WebTV to the same specially designed website. Group 4 consisted of patients who transmitted their glucose measurements via their internet accessible computer to the same specially designed website. Patients who transmitted their glucose measures through a modem were unable to view graphical or tabular representations of their data while patients who transmitted their glucose measures using a WebTV device or personal computer were able to do so. Patients in Group 2, 3 and 4 transmitted their glucose data to their provider weekly. The provider reviewed these data weekly and intervene personally with the patient whenever it was clinically appropriate. All research groups also received standard Diabetes Institute care as outline above for Group 1.

Patients in an Group 2, 3 or 4 received training to support the technology assigned to their group. Training was administered by the project officer to each participant at the MRF where care was usually delivered. The patient training modules included specially developed educational materials manuals and videotaped instruction (not to exceed 30 minutes).

Patient confidentiality was protected by identifying patients only by a unique serial number on their glucometer, regardless of the technology used. This number and the patient's identifying information was known only to the providers and Principal/Associate Investigators. Patients who transmit data to the secure Walter Reed website via modem utilized a TCP/IP connection. Patients who transmitted data using WebTV and a personal computer accessed the secure Walter Reed website via an HTTP connection. Non-active duty military patients were paid $150 for participation in the study.

c. Technology:
The software development and maintenance and the establishment of a secure website were performed under contract by HealthSentry, who modified a previously developed proprietary

product for the investigators. This unique software allows the patient to use any brand of glucose meter to download their data into a secure website. The patients entered the website through the WRAMC website. The HS system collects, stores and retrieves glucose data. A server using an Internet Server API (ISAPI) application received the data, verified its integrity, and extracted the glucose meter's serial number from the data for identification purposes. Data and the serial number of the meter was encrypted by RSA/Secure Sockets Layer (SSL) encryption. The software read and formatted the glucose data, compared them to ranges defined for that patient, and added them to the database. Once the data had been uploaded the patient could view the current data with or without previous data. Graphs and charts were created using ISAPI modules, and a variety of pre-set formatting options are available. A hierarchy of users (patients, care providers, others) could log into the site and perform various functions. Patients could view their uploaded data, care providers could create patient accounts and view data from patients assigned to them, and system administrators could perform all functions. The care provider graphing and chart displays were more sophisticated than the patient interface, and data manipulation such as scaling and filtering could be performed. Several graph types (e.g. trend, glucose profile, pie chart) and statistical summaries (e.g. mean, standard deviated, % above and below target) were available. Data uploads, logins, and account creation/ deletion) were recorded in the database and monitoring reports will analyze these data. Patient uploads and graph/chart creation were performed in C++ for minimum system load. The care provider interface was primarily written in ASP and Java; graph and chart data could be dynamically reformatted and downloaded to the care provider's computer and locally manipulated with C++ ActiveX controls. The database design included features for the annotation of data points or datasets (groups of downloaded data points).

The data was automatically analyzed and displayed in both numeric and graphic formats. All Principal and Associate Investigators had continued free and open access to the secured patient data. HealthSentry produced a patient training module that included manuals, user's guides, and videotapes. These specially developed educational materials are owned by WRAMC and maintained on the facility. HealthSentry maintained an 800 # Hot Line for support. The only patient data resident in the HealthSentry database is the patient's glucometer serial number and blood glucose levels.

KEY RESEARCH ACCOMPLISHMENTS

Our study sheds some light on the feasibility of using a web-based data analysis and graphic display system for monitoring and managing patients with diabetes mellitus. As outlined above, we provided poorly controlled diabetics (A_{1c} > 8.0%) referred to the Diabetes Institute (DI) of the WRHCS with one of three technologies to communicate their blood sugar results from home to their provider for 6 months. One hundred and sixty-seven patients were recruited into the study. They were randomized to "routine care" (n=67) or "technology" (n=104). Patients in the latter group were further randomized to one of three technologies – modem (n=37), WebTV (n=22), internet accessible computer (n=45). The data on the first nine-two patients who have completed the study are presented here. These ninety-two patients were randomized as follows: "routine care" (n= 45; 22 women and 30 men) or "technology" (n= 47; 36 women and 52 men). Both the "routine care" and "technology" groups were followed by endocrinologists or by endocrine-trained nurse practitioners who had at least 1 year of extensive DM management experience. Patients in the "technology" group were further randomized to one of three technologies - modem, WebTV, and internet accessible computer - which enabled them to transmit data from their glucose meter to their provider via a secure password-protected website maintained by HealthSentry (HS) (www.HealthSentry.net). Patients in the WebTV and computer groups also could review their own data on the website while those in the modem group could not. Since the data from each of the 3 technology groups were statistically indistinguishable, they were grouped for further analysis.

"Routine care" patients were seen in the clinic as needed but no less than every 3 months and received treatment according to clinical practice guidelines established by the DI. The patients in the "technology" group were similarly treated, but also uploaded their blood glucose values weekly using the assigned technology. The data were analyzed and displayed in tabular and graphic formats (sample data can be viewed by using the Logon ID = VCRSG and Password = 7260 at www.HealthSentry.net and selecting patient "Rosalie."). Treatment recommendations then were made by the provider based on the HBGM data combined with the other information obtained from the patient. Over six months, patients receiving "routine care" significantly improved their mean (± sem) serum glucose (206.5 ± 14.2 mg/dl to 168.2 ± 13.4 mg/dl; $p < 0.01$) and their A_{1c} (10.05 ± 0.32 % to 8.32 ± 0.30%; $p < 0.01$). However, the improvement in glycemic control was associated with a weight gain from 215.9 ± 18.6 pounds to 223.3 ± 18.3 pounds; $p < 0.01$) .Those in the "technology" group had similar improvements in serum glucose 180.5 ± 10.3 mg/dl to 148.9 ± 7.7 mg/dl; $p < 0.01$) and their (9.55 ±0.24% to 7.83 ± 0.22%; $p < 0.01$) but without significant weight change (230.2 ± 13.3 pounds to 229.6 ± 13.2 pounds). The "technology" group did not improve glycemic control significantly more than those receiving " routine care," nor were there differences among the three different "technology" groups in glycemic parameters. Lipid studies revealed that those in both groups had statistically significant reductions in total and LDL cholesterol but the triglycerides went up with "routine care" (194.4 ± 16.4 mg/dl to 212.8 ± 23.5 mg/dl) and down with "technology" (182.8 ± 13.6 mg/dl to 167.2 ± 15.2 mg/dl). HDL cholesterol remained unchanged in both groups. There were no differences after 6 months in blood pressure, urine microalbumin/creatinine ratio, hemoglobin, AST, or ALT. The Diabetes Treatment Satisfaction Questionnaire scores were also unchanged over the six month period in both groups. The number of office visits in 6 months was slightly but not

significantly fewer in the "technology" group (2.7± 0.3) compared with "routine care" (3.2 ± 0.3). The "technology" group had a higher number of telephone consultations (8.4 ± 0.7 vs. 4.6 ± 0.7; $p < 0.005$).

These data indicate that telemedicine technologies did not improve glycemic control above that of "routine care," where the "routine care" setting is a highly specialized referral clinic. However, the improved glycemic control was accomplished without the usual accompanying weight gain. Furthermore, the triglyceride levels, an independent risk factor for coronary artery disease, improved in the "technology" groups but worsened in those getting "routine care." We hypothesize that the ability to show any advantage in the primary outcome measures of this study, i.e. glycemic control, in the "technology" groups may have been limited by the fact that patients in both "technology" and "routine care" groups were treated by endocrinologists and specially trained and experienced nurse practitioners. Thus, those in the "routine care" group had their glucose data both reviewed and acted upon in a similar and appropriate way as those in the "technology" group. Since the protocol directed that there be a clinic visit at least every three months, the possibility of finding a difference in the time between visits was limited.

REPORTABLE OUTCOMES

There are a number of important results of this study:

1. A web based glucose management system using any one of the three technologies tested is technically feasible.
2. Of the three technologies used, the internet accessible computer system is the most flexible and cost-effective since it allows patients to view their data and the cable to connect their Accu-chek meter to the computer is inexpensive.
3. The Web-TV system was the most expensive because of the cost of the subscription and also had the most technical problems associated with it.
4. The HealthSentry software system has proven to be robust and flexible. It appears to be infinitely expandable allowing for potential AMEDD and DoD-wide application.
5. The HealthSentry contractors produced all deliverables in the Statement of Work in a timely fashion.
6. Telemedicine technology resulted in improved glycemic control similar to that of "routine care" but without weight gain and elevation in serum triglycerides.
7. The improvement in glycemic control was achieved with 0.5 fewer clinic visits per 6 months. Extrapolated over 1 year, this would reduce the significantly reduce number of clinic visits by patients with diabetes in the WRHCS.
8. The failure to show a difference between the "routine care" and "technology" groups in glycemic control, per se, is a most likely due to the sophisticated and high-quality care provided by the specialty-trained nurse practitioners who treated the vast majority of patients.

The results of this study point to the need for further investigation into using these technologies in the primary care setting. While the Diabetes Institute of the Walter Reed Health Care System has evaluated about half of the 6000 patients with diabetes in the Washington D.C. metropolitan area over the past 3 years, the vast majority of the on-going care of these patients is performed by Internists, Family Practitioners, Nurse Practitioners, and Physician Assistants. It is my hypothesis that this is the group that is most likely to benefit for the use of the technology developed in this study (see conclusions below).

a) **CONCLUSIONS**

This study forms the foundation for a Telemedicine Diabetes Research Program whose vision is to use telemedicine technologies in disease management to leverage the ability of a diminishing number of health care providers to manage the rapidly increasing number of diabetics and to do so with improved outcomes. By their very nature, the technologies are capable of being deployed AMEDD and DoD-wide.

The follow-on projects to the current study and their operational/funding status are outlined below. Several protocols that are related to the Comprehensive Diabetes Management Program (CDMP) are not itemized in the table. They include:

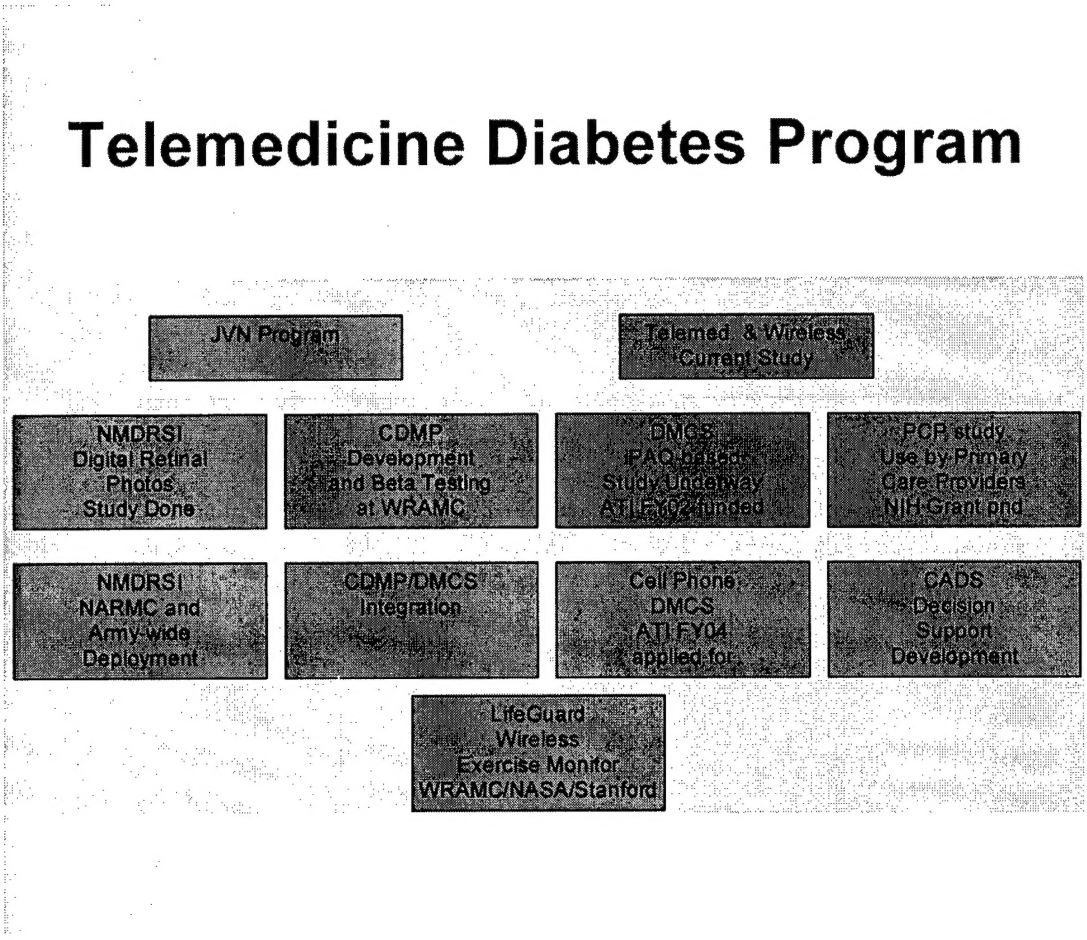
a) a cost-effectiveness analysis
b) a clinical outcomes assessment
c) development/validation of an on-line tool to assess learning level and readiness to learn
d) validation of the Behavior Assessment Tool which has been developed for CDMP (includes 46 questions about a diabetic patient's physical wellness, lifestyle and self-management, and psycho-social status) and will be administered on-line

Project	Description	Status
Comprehensive Diabetes Management Program (CDMP)	An electronic medical record to capture and display the overall disease status of a diabetic patient for the care manager. It will include input from the NMSDRI (v.i.) and DMCS as well as multiple providers involved in diabetes care, e.g. dietitian, educator, exercise physiologist. It has been a collaborative effort of DoD, Veterans Health Administration, and Indian Health Service.	A beta-test version has been developed and is awaiting approval from DOIM at WRAMC for installation and integration into the ICDB (Integrated Clinical Data Base). It is designed to be integrated into Tricare Online and into CHCS 2. Funding - USAMRMC Log #98048002 COR: Ron Poropatich
Non-Mydriatic Stereoscopic Digital Retinal Imaging (NMSDRI) - Joslin Vision Network (JVN)	Use NMSDRI at 4 MTF's in the Walter Reed Health Care System to screen for diabetic retinopathy with the goal to replace the yearly dilated exams in those who are found to be normal by JVN. Interpretations and photos will be incorporated into CDMP.	Initial assessment completed in10/03 showing high sensitivity and specificity for screening. Goal is to: 1) incorporate the results into the electronic medical record; and 2) deploy this AMEDD based on these results and assessment of cost-effectiveness. Funding via USAMRMC COR: Ron Poropatich
Diabetes Management and Communication System (DMCS)	Insulin pump users are given IPAQ's which are programmed with an algorithm for calculating insulin doses based on glucose, carbohydrate intake, exercise, and insulin/exercise sensitivity. Data is wireless transmitted to the web site of HealthSentry which has been modified to accept, analyze, and graph the additional data	DCI-approved protocol is currently in progress. Addendum to DCI-approved protocol expanding to non-pump users taking 3 or more shots per day was approved. Funding via FY02 Telemedicine Initiative Proposal Number: 2001011202

Management of Diabetes with Telemedicine	Assessment of the efficacy of a web based diabetes and blood pressure management system in the hands of Primary Care Providers some of whom are given computer-assisted decision support for therapeutic recommendations.	Selected as a finalist for the 2002-3 Robert Wood Johnson TeleHealth Initiative. NIH grant (1 R18 DK067203-01) submitted 1 JUN 03 in response to RFA "Translational Research for the Prevention and Control of Diabetes"
The Development of a Computer-Assisted Decision Support System for the Management of Patients with Diabetes Mellitus	Development and preliminary testing of a computer-based decision support system for the management of diabetes	FY04 AMEDD Telehealth Initiative Pre-Proposal submitted #2003011121
A Cell Phone-Based Diabetes Management and Communication System (DMCS)	Programming, testing, and deploying a cell phone-based DMCS to take advantage of advanced capabilities and lower cost of cell phones compared to personal digital assistants	FY04 AMEDD Telehealth Initiative Pre-Proposal submitted #200311150
Improving Insulin Dosing in Patients with Type 1 Diabetes Mellitus Using a Wireless Physiologic Monitoring System	Using the wireless Lifeguard physiologic monitoring system (NASA/Stanford) to assess the affects of exercise on insulin sensitivity and apply the results to the DMCS	Applied for funding from Technologies for Metabolic Monitoring 2003 (DAMD17-BAA-TMM03): PI – Greg Kovacs

While expansion of the use of HealthSentry Diabetes Monitoring System to the WRHCS, NARMC, and AMEDD will require the purchase of license which may cost up to $200,000, if this technology is successful in a Primary Care setting, there are significant financial implications. The most conservative estimate of the economic benefit of better diabetes control is that there is a savings of $400 per diabetic patient per year if the Hemoglobin A1c is reduced from 8-10% to under 8%. The projected savings would be about $1 million per year for the 2500 patients in the WRHCS with A1c's above 8% and 10 times that AMEDD-wide.

The integration of these various projects is shown in graphic form below. The current study is on the upper right. The status of the other studies are listed above.



FUNDED PERSONNEL AND PARTICIPANTS

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PRESENTATIONS, POSTERS, PUBLICATIONS

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